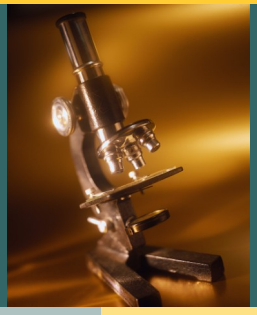
Winter 2009



NORTH DAKOTA DEPARTMENT OF HEALTH
DIVISION OF HEALTH FACILITIES

CLIA BITS

Microbiology Media Quality Control

CLIA regulations require quality control of media. Each batch of media must be checked for sterility and the ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response. The laboratory must document the physical characteristics of the media when compromised and report any deterioration to the manufacturer. A batch is defined as the same media prepared at the same time and in the same laboratory; or media that has the same lot number and is received in the same shipment from an outside source. A sample from each batch should be checked for the following: sterility; ability to support growth using at least one organism; selectivity, using at least one organism to confirm its selective characteristic; inhibition, using at least one organism to confirm its inhibitory characteristic; and biochemical response, using at least one organism that will produce the expected reaction as a positive control and at least one organism that will not produce the expected reaction as a negative control.

An exception to media quality control will be made if a laboratory uses commercially prepared media that is quality controlled in accordance with the Clinical and Laboratory Standards Institute (CLSI), formerly National Committee for Clinical Laboratory Standards, Approved Standard Table 2. The laboratory must have documentation from the manufacturer showing its quality control practices conform to CLSI specifications. The laboratory is required to document receipt and condition of each batch of media. The laboratory must notify the manufacturer of cracked petri dishes, unequal filling, cracked media, hemolysis, freezing, excessive bubbles and contamination.

The exception does not apply to the following media:

- Campylobacter agar
- Chocolate agar
- Media for the selective isolation of pathogenic Neisseria
- Other media not listed on CLSI Table 2
- Media used for isolation of parasites, viruses, mycoplasma, Chlamydia
- Mueller-Hinton media used for antimicrobial susceptibility
- Commercially prepared media packaged as a system consisting of two or more different substrates, primarily used for microbial identification.

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If you would like to receive CLIA Bits electronically, please send your e-mail address to Bridget Weidner at bweidner@nd.gov.

Most Commonly Cited Deficiencies

Following is a breakdown of the most common deficiencies cited in the North Dakota CLIA program from Oct. 1, 2007, through Sept. 30, 2008.

D5439—Calibration and Calibration Verification. The laboratory must verify calibration at least once every six months. For exceptions, see the CLIA regulations at 493.1255(b). Laboratories should check electrolyte calibrations. Most electrolytes are calibrated with less than three levels of calibrator, therefore, not qualifying for the exception to calibration verification.

D6093—Laboratory Director Responsibilities. The laboratory director must ensure quality control programs are established and maintained to ensure the quality of laboratory services provided and to identify failures in quality as they occur. This includes ensuring the correct International Normalized Ratio (INR) calculations.

D2016—Successful Participation. Each laboratory performing non-waived testing must successfully participate in a proficiency testing program.

D5413—Test Systems, Equipment, Instruments, Reagents. The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens. These conditions must be monitored and documented.

D5429—Maintenance and Function Checks. The laboratory must perform and document the performance of maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

D5217—Evaluation of Proficiency Testing Performance. The laboratory must verify the accuracy of any non-regulated analyte at least twice a year.

D5421—Verification of Performance Specifications. The laboratory must demonstrate it can obtain performance specifications comparable to those established by the manufacturer for accuracy, precision and reportable range. The laboratory must determine reference intervals are appropriate.

Questions and Answers (Q & A)

CMS provides specialized CLIA training courses for state surveyors. During these training courses, surveyors from across the country ask CMS staff questions regarding the survey process. Although the questions and answers do not represent official CMS policy, they contain valuable information regarding the survey process. The Q & A is a regular feature of the CLIA Bits newsletter. We hope you find this information interesting and useful. Readers are welcome to submit questions to bweidner@nd.gov or sheilman@nd.gov.

Q. How long should the lab retain initial instrument validation records?
A. For the period of time the lab uses the instrument, but no less than two years.

Q. Can the laboratory director delegate the responsibility of signing new procedures?
A. The writing of the procedure may be delegated, but the laboratory director must approve, sign and date the procedure.

Q. If the manufacturer does not require maintenance and/or function checks, can the lab state none need to be performed?
A. Yes, if the lab has determined none is needed. However, if the lab determines a maintenance and/or function check protocol is necessary to ensure accurate and reliable test results, the lab must establish a protocol and perform and document the activities.

Critical Values

CLIA regulations state the laboratory must immediately alert the provider of any test result indicating an imminently life-threatening condition or panic value. The laboratory should document the date, time, test results and person to whom results were reported. How does your laboratory monitor that panic values are reported in a timely manner? Did you know most laboratory information systems are capable of tracking critical values? Does your laboratory routinely review the established panic values to see if changes are needed? Does your critical value policy address what the laboratory should do if the provider is not available to receive the report? Are laboratory testing personnel familiar with the critical value policy?

Microbiology Media Quality Control (Continued from page 1)

The laboratory is required to perform its own quality control testing for these types of media.

The laboratory is not required to use American Type Culture Collection (ATCC) control organisms for quality control testing. If "in-house" isolates are used for control organisms, the laboratory must have established reactivity for each organism. If the laboratory sets up cultures and reports "No growth" and refers growth to a reference laboratory, the laboratory must perform applicable media quality control.

For more information regarding CLSI, visit their website at www.clsi.org.

Upcoming Meetings and Seminars

- Rolling Out the Red Carpet for Laboratory Professionals
  ASCLS-ND Annual Spring Meeting
  April 22-24, 2009 in Grand Forks
  For speaker and registration information, visit www.asclsnd.org and click on Meetings and Events.

- Point of Care Testing Seminar
  Sponsored by the St. Alexius Point of Care Testing Department
  March 5, 2009; 12 p.m. to 5 p.m.
  For speaker and registration information, please contact Margie Vossler at mvossler@primecare.org or at 701.530.6782.

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